

## REMARKS

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 139-155 and 157-163 are pending in the present application.

Claims 29 and 156 are currently cancelled without prejudice or disclaimer to the subject matter recited there.

Claims 1 and 21 have been amended to recite the ratio range of water to alcohol as "1:1 to 1:3" and to remove "a hair generating agent" from the possible optional excipients.

Support for the amendments appears throughout the specification and claims as originally filed. No new matter has been added. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original claim scope of any claim amended herein, in a continuing application.

In view of the following, further and favorable consideration is respectfully requested.

**INDEFINITENESS REJECTION**

***Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-163 are rejected under 35 USC 112, 2<sup>nd</sup> Paragraph, as Being Indefinite***

Applicants traverse this rejection. However, to clarify the issue, Applicants submit that claims 1 and 21 have been amended to remove the grounds for the rejection without any prejudice or disclaimer to the original subject matter discussed therein. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**OBVIOUSNESS REJECTIONS BASED ON JP 10-265343**

- A. Claims 1, 3-4, 8, 12-16, 19, 26, 29, 139, 141, 143-144 and 162 are rejected as obvious over JP 10-265343 in view of Yu et al.***
- B. Claims 21, 23-24, 146-151, 153-157, 159-160 and 163 are rejected as obvious over JP 10-265343 in view of Yu et al. and Chow et al.***
- C. Claims 152 and 161 are rejected as obvious over JP 10-265343 in view of Yu et al. and Chow et al. and in further view of Uchikawa et al.***
- D. Claims 140 and 145 are rejected as obvious over JP 10-265343 in view of Yu et al. and in further view of Uchikawa et al.***
- E. Claim 158 is rejected as obvious over JP 10-265343 in view of Yu et al. and***

***Chow et al. and in further view of Peck et al.***

***F. Claim 142 is rejected as obvious over JP 10-265343 in view of Yu et al. and in further view of Peck et al.***

Applicants traverse each of these rejections. The primary reference for each of these rejections, JP 10-265343, does not constitute prior art against the instant application. The instant application has an effective priority date of April 22, 1998, as it properly claims priority to Australian Patent Application No. PP 3107 filed on April 22, 1998. However, the effective date of the JP 10-265343 reference is the date the reference was published, October 6, 1998, which is clearly after the earliest claimed priority date of the present application. Further, Applicants note that the corresponding international publication of this reference, WO 98/32417, took place on July 30, 1998 in Japanese, again after the earliest claimed priority date of the present application. In addition, the WO 98/32417 publication does not bear a 35 USC 102(e) date against the present application since it (1) was filed and published before November 29, 1999 under the “old” 102(e); and (2) in any event, was not published in English. In fact, no document in this family of publications constitutes prior art against the instant application.

Furthermore, claims 1 and 21 have been amended to claim the water to alcohol ratio of 1:1 to 1:3, which is recited in Australian Patent Application No. PP 3107. Thus, the

instant claims are entitled to rely on the Australian priority date in that regard. With respect to the Examiner's allegation that the Australian priority application does not disclose generic excipients, such as higher alcohols, vitamins preservatives, refrigerants, UV absorber, dye or gelling agent, Applicants submit that these are recited in an optional embodiment of the claimed subject matter. As such, they are not material to the patentability of the instant claim. Applicants submit that in this case, whether or not optional embodiments are found in the priority application is thus irrelevant, since their absence or presence is not part of the obviousness analysis.

Accordingly, the primary reference relied on by the Examiner in each of these rejections, JP 10-265343, does not qualify as prior art against the present application. Without the teachings of this primary reference, none of the other cited reference teachings, whether taken alone or in combination, are sufficient to establish a case of *prima facie* obviousness against the present claims. Accordingly, withdrawal of each of the rejections under 35 U.S.C. §103(a) is requested.

#### **OBVIOUSNESS REJECTIONS BASED ON NAVARRO**

***A. Claims 1, 3, 4, 8, 12-16, 19, 26, 29, 139, 143, 144 and 162 as obvious over Navarro et al. in view of Wiener et al. and Yu et al.***

- B. Claims 21, 23, 24, 146-151, 153-156, 159, 160 and 163 as obvious over Navarro et al. in view of Wiener et al., Yu et al., and Chow et al.***
- C. Claims 140 and 145 as obvious over Navarro et al. in view of Wiener et al. and Yu et al. and further in view of Uchikawa et al.***
- D. Claims 152 and 161 as obvious over Navarro et al. in view of Wiener et al., Yu et al., and Chow et al. and further in view of Uchikawa et al.***
- E. Claim 142 as obvious over Navarro et al. in view of Wiener et al. and Yu et al. and further in view of Peck et al.***
- F. Claim 158 as obvious over Navarro et al. in view of Wiener et al., Yu et al., and Chow et al. and further in view of Peck et al.***
- G. Claim 141 as obvious over Navarro et al. in view of Wiener et al. and Yu et al. and further in view of Gibson***
- H. Claim 157 as obvious over Navarro et al. in view of Wiener et al., Yu et al., and Chow et al. and further in view of Gibson***

Applicants traverse each of these rejections. Applicants submit present claim 1 recites the transition language “consisting of.” Claim 21 recites providing a pharmaceutical composition “consisting of.” This transition language excludes components other than those expressly recited. Accordingly, claims 1 and 21 clearly exclude encapsulation in lipid vesicles and/or in a cyclodextrin carrier. The other rejected claims all depend directly or

indirectly from one of these independent claims, and thus contain all of the limitations of these independent claims.

Navarro et al. describe encapsulating minoxidil in a cyclodextrin carrier, wherein cyclodextrin functions as a “host” molecule to trap the minoxidil “guest” molecule inside the ring. Navarro et al. describe the use of cyclodextrin in order to assist in the solubilization of minoxidil while avoiding high amounts of propylene glycol. Navarro et al. state the following:

[t]he amount of  $\gamma$ -cyclodextrin present in the composition for hair is such that it permits a substantial reduction in the amount of solvent for minoxidil which would normally need to be added to achieve a comparable solubility of minoxidil in the absence of the aforementioned cyclodextrin. (Page 3, lines 9-13 of the English translation).

From the foregoing, it is clear that cyclodextrin is an essential element of Navarro et al. because it must be combined with minoxidil in order to impart improved solubility properties to minoxidil, thereby reducing the amount of solvent such as propylene glycol needed in the formulation. However, the present claims **exclude** cyclodextrin. As such, the encapsulating technique of Navarro et al. is distinguished.

The Declaration submitted previously on November 8, 2007 further supports the foregoing. The Declaration under 37 CFR §1.132 by Albert Zorko Abram (“the Abram

Declaration”), was filed in corresponding patent application serial no. 10/124,197, now U.S. Patent No. 6,946,120, in response to a rejection of the pending claims under 35 USC § 103 as obvious over the disclosure of Navarro in view of Weiner et al. and further in view of Leitch.

In the Declaration, Mr. Abram declares in paragraph 9 that supplementing the teaching of Navarro with the teaching of Weiner et al. **would destroy the intended purpose of the Navarro composition.** Mr. Abram declares in paragraph 10 that the role of cyclodextrin in Navarro is to function as a host molecule to trap the minoxidil “guest” molecule inside the ring and that it is the minoxidil-cyclodextrin “host-guest” complex that imparts improved solubility properties, as compared to a similar minoxidil composition not having cyclodextrin. Mr. Abram declares that it is recognized that cyclodextrins are unstable in acidic conditions and that subjecting cyclodextrins to acidic conditions will result in the degradation of the cyclodextrins into their individual glucose units.

None of the secondary references, taken alone or in any of the cited combinations, remedies the deficiencies of Navarro.

In view of the foregoing, it is submitted that nothing in Navarro et al., along with the various combinations of secondary references, taken alone or together, renders the

presently pending claims obvious within the meaning of 35 USC § 103. Accordingly,  
withdrawal of each of the rejections under 35 U.S.C. §103(a) is requested.



## **CONCLUSION**

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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